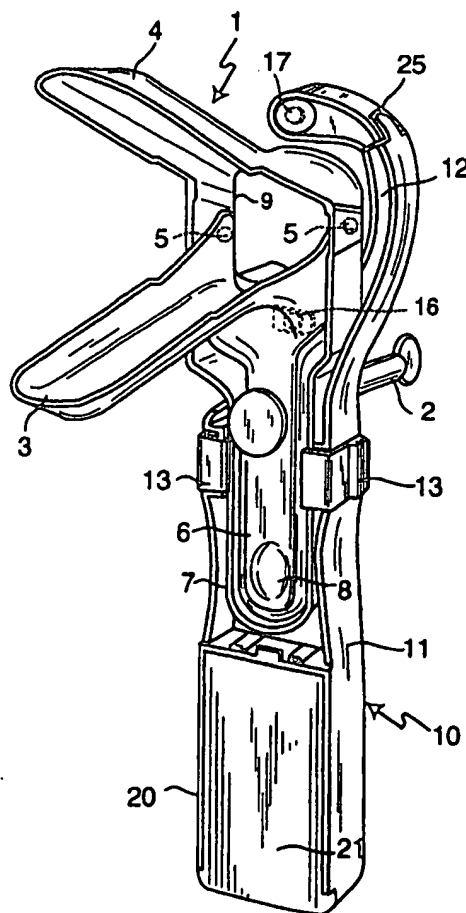


## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<b>(21) International Application Number:</b> PCT/IT97/00301 <b>(22) International Filing Date:</b> 5 December 1997 (05.12.97) <b>(30) Priority Data:</b> RM96A000866 13 December 1996 (13.12.96) IT <b>(71) Applicant (for all designated States except US):</b> SOLUTION S.A.S. [IT/IT]; Via A. Pacinotti, 6b, I-00146 Roma (IT). <b>(72) Inventor; and</b> <b>(75) Inventor/Applicant (for US only):</b> MIONI, Franco [IT/IT]; Solution s.a.s., Via A. Pacinotti, 6b, I-00146 Roma (IT). <b>(74) Agents:</b> BANCHETTI, Marina et al.; Ing. Barzandè & Zanardo Roma S.p.A., Via Piemonte, 26, I-00187 Roma (IT).		<b>(81) Designated States:</b> AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>With international search report.</i>

**(54) Title:** LIGHT AND HANDLE DEVICE FOR VAGINAL SPECULUM**(57) Abstract**

A light and handle device for a vaginal speculum is described comprising at one end a handle portion (11) having an elongate shape and at the other end a shaped lighting portion (12) having a curved shape and, at an intermediate position between the said two ends, pliers-like fixing means (13) for rigidly connecting the device (10) with the upper gripping arm (7) of an ordinary speculum (1). The handle portion (11) has higher dimensions than the upper gripping arm (7), thus resulting in an ergonomic grip. The shaped lighting portion (12) has a curved profile which, when the speculum (1) is connected with the device (10), follows from the exterior the outline of the speculum mouth (9), and is provided with one or more light sources (16, 17) placed along its inner edge and facing towards the speculum mouth (9).



# LIGHT AND HANDLE DEVICE FOR VAGINAL SPECULUM

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**Applicant:** SOLUTION S A S (IT);; MIONI FRANCO (IT)  
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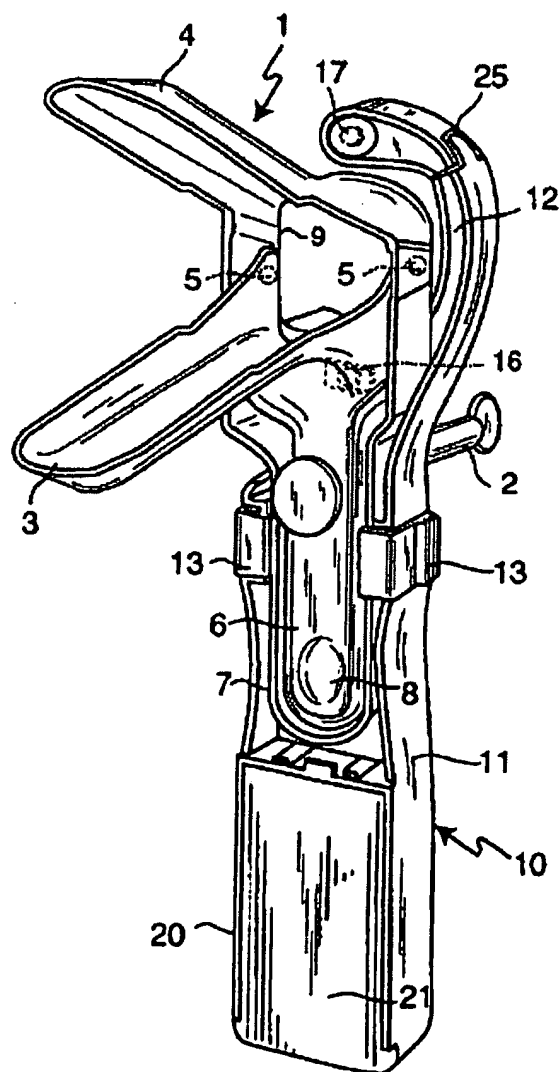
**Cited documents:**

US4619248  
 US4502468  
 EP0407357

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**Abstract of WO9825512**

A light and handle device for a vaginal speculum is described comprising at one end a handle portion (11) having an elongate shape and at the other end a shaped lighting portion (12) having a curved shape and, at an intermediate position between the said two ends, pliers-like fixing means (13) for rigidly connecting the device (10) with the upper gripping arm (7) of an ordinary speculum (1). The handle portion (11) has higher dimensions than the upper gripping arm (7), thus resulting in an ergonomic grip. The shaped lighting portion (12) has a curved profile which, when the speculum (1) is connected with the device (10), follows from the exterior the outline of the speculum mouth (9), and is provided with one or more light sources (16, 17) placed along its inner edge and facing towards the speculum mouth (9).





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## LIGHT AND HANDLE DEVICE FOR VAGINAL SPECULUM

### Description of WO9825512

#### LIGHT AND HANDLE DEVICE FOR VAGINAL SPECULUM

The present invention concerns a light and handle device for a vaginal speculum. More specifically, the invention concerns an accessory which may be connected to a normal vaginal speculum, providing direct illumination of the zone to be examined and, at the same time, providing a gripping element which increases the ease of handling the speculum.

As it is known, the instrument currently referred to as vaginal or gynaecological speculum consists of two blades or paddles, usually pivotally connected to each other in proximity of the speculum mouth, which define, with their substantially cylindrical surfaces, rounded at the ends and matching when in the closed position, a tubular shape easily insertable in the vaginal cavity. After the insertion the two blades are moved apart from one another, generally by relative rotation or, in some speculum types, by sliding relative to one another, and then they are blocked in the open position, in order to dilate the vaginal cavity to allow visual examinations, biopsies for cytological and histological analysis and medical interventions, in particular on the zone of the cervix uteri.

The speculum mouth, which in the most widespread versions opening by relative rotation is placed in proximity of the hinge axis of the two blades, defines a passage window. Any instruments, such as sampling spatulas, are to be introduced through this window, and through this window the physician has to carry out the visual examination, if needed with the help of optical means. Normally, the speculum mouth is limited by an upper annular opening integral with one of the two blades. The opening is prolonged, on the side diametrically opposed to that on which the blade is connected, in a gripping arm making an obtuse angle with the blade. The other blade is in turn provided with a second gripping arm which is intended to be acted upon together with the first arm to move the device in the open position. In the speculum types opening by rotation the second gripping arm defines with the corresponding blade an angle which is narrower than the angle between the first arm and the relevant blade. As a consequence, when the two blades abut on one another the two arms are in a divergent relative position, and when the ends of the two arms are moved close to each other (usually by pressing them between index-finger and thumb) until they are equally oriented the two blades diverge, thus dilating the body cavity to be examined.

The various types of vaginal speculum in use also differ in the material of which they are made, as they may be made of metal, and be reusable after sterilisation, or of plastic material, either transparent or not, and be disposable after use. The said speculum types may also differ in the configuration of some secondary elements, such as the means for adjusting and blocking the device in the open position. As concerns the latter aspect, the two most diffused blocking systems for specula which open by relative rotation of the blades are the lateral screw system and the central pin system.

The lateral screw system consists of a screw pin fixed, so as to be rotatable about its axis, to the gripping arm of the lower blade in proximity of the point where the arm joins the blade. The screw laterally projects in a direction orthogonal to the gripping arm, and passes through an internally threaded eyelet provided in the corresponding position at the base of the gripping arm of the upper blade. The screw rotation results in the relative displacement, adjustable, of the two arms, and of the two blades connected thereto. The second blocking system, i.e. the central pin system, consists of a pin or nail having a non-circular cross section, which passes through a hole and a corresponding slot, made in the middle of each of the gripping arms, close to the points where the said arms join the corresponding blades. Once the speculum has been inserted and opened, the relative position of the two blades is blocked by rotating the pin about its axis, so as to make the portion of lateral surface thereof having a higher diameter frictionally interfere with the margin of the slot of the upper gripping arm.

It is clear that during a medical examination or intervention employing a speculum, the gynaecologist has to be able to rely on a suitable illumination, reaching and striking the concerned internal tissue zones with a sufficient intensity and a correct orientation. Various lighting systems in use in medical consulting rooms are normally employed to meet the said need, such as fixed lights and reflectors, stroboscopes, optical fiber illumination means, as well as flashlights and reflectors that the gynaecologist or his assistant have to hold with one hand or with other parts of their body. Such systems unavoidably bring about training

problems, and suffer from the presence of obstacles which may lie between the light source and the zone to be examined, besides being often inconvenient to use. In addition, the specialist has in any case to have recourse to the only use of flashlights or other portable equipment when carrying out examinations out of his consulting room.

Portable devices which are able to supply an illumination directly associated with the speculum function are already known in the art. In particular, US patent No. 3,716,047 discloses a disposable speculum made of plastic material which is releasably connected to a light source provided with a tubular guide with optical fibers. The light source is connected with the lower gripping arm or leg portion of the speculum, so as to form a kind of handle.

Within the lower blade of the speculum there is provided a curved channel having rectangular cross section, which follows the bend from the leg portion to the blade and acts as a guide for the light beam projected by the optical fibers, directing it towards the distal end of the blade. The device disclosed is in practice a disposable speculum of a special construction and not a lighting device applicable to commercial specula already in use. Its structure requires higher production costs for the disposable element.

A light device applicable to standard vaginal specula is disclosed in US patent No. 4,067,323, consisting of a small battery-operated bulb enclosed in a planar configured casing. The latter can be frictionally connected astride the edge of the speculum mouth, on the side opposed to that on which the gripping arm is joined. The light bulb is placed facing the interior of the speculum mouth, towards the blades. It is clear that such a device is a means of illumination which can be associated with the commercial specula; however, the said device does not supply any accessory means to help in handling the speculum. In addition, the device disclosed comes into direct contact with the speculum mouth and for this reason the document proposes, in order to safeguard the sterility of the device, to protect it with a throw away flexible transparent plastic bag.

A different lighting system, which supplies an illumination specific for some diagnostic purposes, is disclosed in US patent No. 5,179,938, which proposes the use of a chemiluminescent tubular container. The latter is activated by breaking an internal wall which separates, within the container, two chemicals. The reaction of the two chemicals produces a light with wavelength peaks in the range of green and blue, which is particularly suitable for evidencing some abnormalities of the vaginal and/or cervical mucosal membranes. In the concerned patent the tubular container is fixed, longitudinally oriented, at the interior of the upper blade of a vaginal speculum, the latter being either made of metal or of transparent plastic material, and being provided with proper means for retaining the tubular container in the desired position.

A device quite similar to the previous one is disclosed in PCT application publ. No. WO 95/13009, wherein the only difference is in the shape of the housing for holding the chemiluminescent container in place, having two retention walls for housing the container in a snap-fitting engagement within the upper blade of the speculum.

Both devices referred to above, therefore, are speculum models of special construction, rather than light systems applicable on any kind of speculum already in use. The commercial evolution of US patent No.

5,179,938 on the chemiluminescent tubular container, however, has overcome the need of a speculum of special construction, as it makes use of a stripe of double sided adhesive tape, which can be placed within the upper blade of any ordinary speculum.

None of the two above devices, nor the connected commercial solution, however, are provided with additional elements suitable to make the gripping of the speculum easier, nor they are proposed for use in combination with means having such a function.

Therefore, the object of the present invention is to provide a lighting device directly applicable to any kind of vaginal speculum and easily detachable from it upon use, capable of projecting its light on the zone of interest for the direct visual examination of the vaginal mucous membrane and, at the same time, capable of making the handling and the insertion of the speculum easier, thus providing an ergonomic gripping element.

To this aim there is proposed, in accordance with the present invention, an instrument having a substantially elongate shape, provided with a grasping element in order to be rigidly connected to the

upper gripping arm of the speculum, thus overlying said arm and appreciably increasing its size so as to realise a kind of handle. The proposed instrument also comprises, at the end thereof intended to be superimposed, in use, on the speculum mouth, a curved arm which follows the outline of the said mouth and includes one or more light sources, placed along the said arm and facing towards the speculum. The light sources are preferably powered by batteries or rechargeable cells housed within the instrument body, on the side opposed to the curved arm. The shape of the instrument is designed to allow its coupling both with the specula with lateral screw blocking system and with those with central pin blocking system. In all cases the coupling is such as not to hinder the opening and closing movements of the speculum and the functionality of the said blocking systems.

Therefore, the present invention specifically provides a light and handle device for a vaginal speculum comprising at one end a handle portion having a substantially elongate shape and at the other end a shaped lighting portion having a curved shape and, at an intermediate position between the said two ends, pliers-like fixing means for rigidly connecting the device, with the longitudinal axes parallel, with the upper gripping arm of an ordinary speculum, the said handle portion having higher dimensions than said upper gripping arm, and the said shaped lighting portion having a curved profile which, when the speculum is connected with the device, follows from the exterior the outline of the speculum mouth, and being provided with one or more light sources placed along its inner edge and facing towards the said speculum mouth.

Preferably, the said one or more light sources are powered by disposable or rechargeable batteries housed within the end of the handle portion. It is also possible, however, to design the whole instrument as a single-use throw away item, without any rechargeable or renewable power source.

According to one specific embodiment, the device according to the invention comprises batteries housed at the distal end of the handle portion, beyond the length of handle portion which houses, when the speculum is connected with the device, the said upper gripping arm of the speculum.

For an optimal employment of the instrument as lighting means, the said one or more light sources are two, placed in such positions as to leave the visual and operating window free, and designed so as to direct their converging light beams on a focus point which is the one of interest for the specialist. In particular, the said two lights are in a diametrically opposed position along the inner edge of the said shaped lighting portion, and preferably the first light is placed on the longitudinal axis of the said handle portion, and the second light is placed in a diametrically opposed position, on the extension of the same axis. Advantageously, the latter may be assembled on a terminal section of the said lighting portion which is hinged to the remainder of the device, so as to be adjustably positioned.

Further structural and functional features of the device according to the invention are specified in the further dependent claims. The said features, as well as the advantages of the invention, will be clearer with reference to a specific embodiment thereof, which is shown by way of example only in the accompanying drawings, wherein:

Figure 1 is a perspective view of a current design of vaginal or gynaecological speculum, of the disposable kind made of clear plastic material;

Figure 2 is a perspective view of an embodiment of the light and handle device according to the invention, suitable for being coupled with the speculum of Figure 1;

Figure 3 is a perspective view of the speculum of Figure 1 and of the device of Figure 2 assembled together, in the working position;

Figure 4 is a side elevation view of the same speculum-device assembly of Figure 3;

Figure 5 is a top plan view of the same light and handle device of the previous figures;

Figure 6 is a plan view from the bottom of the same device;

Figure 7 is a plan view from the bottom of the same device, without the bottom covers; and

Figures 8 and 9 are two side elevation views, from the right and from the left hand-side, of the same device.

The speculum (1) shown in Figure 1 is one of the types of disposable speculum made of transparent plastic material presently available on the market, of the kind with central pin (2) means for blocking the device in the open position. The lower blade (3) and the upper blade (4), by rotating relative to one another about the pivots (5), may pass from a totally closed position, with the edges practically matching, to a totally opened position such as that shown in figure 1. At the same time, the lower gripping arm (6) and the upper gripping arm (7) pass from a position of maximum divergence to an abutment position, with the axes parallel to each other, such as that shown in the figure. Once this position (or, if desired, an intermediate position) is reached, the pin (2), having an elliptical cross-section, is made to rotate about its

axis so as to interfere, with the portion of higher diameter of its lateral surface, with the margins of the elongate slot (not shown) provided on the upper gripping arm (7), through which said pin (2) passes. The opening step of the speculum (1) is carried out by the gynaecologist by pressing between index-finger and thumb the two gripping arms (6) and (7) at the point where there is visible the contoured surface (8). As it can be seen in Figure 1, the mouth (9) of the speculum (1) is defined by the annular opening interposed between the upper blade (4) and the upper gripping arm (7).

The speculum (1) may be coupled to a handle and light device (10) according to the invention of the kind depicted in Figure 2, as shown in Figures 3 e 4. The device (10) comprises a handle portion (11) which, in the assembled position, embraces and exceeds in length and width the upper gripping arm (7) of the speculum (1), and a curved lighting portion (12) which follows from the exterior the mouth (9) of the speculum (1). The said lighting portion (12) is shaped in such a way as to avoid any hindrance in the visual field of the operator. The coupling between the speculum(1) and the device (10) of the invention is obtained by means of pliers means (13), designed to firmly grasp the upper gripping arm (7) of the speculum (1), while leaving the lower gripping arm (6) free. As a result, the normal opening and closing movements of the speculum(1) are not hindered.

As it is shown in Figure 2, as well as in the views of Figures 5-7, the device (10) according to the invention is provided, at an intermediate position of its length, with an elongate hole (14), through which the central pin (2) of the blocking system may pass and may easily be acted upon. It is to be noted that the same embodiment of the light and handle device (10) shown in the attached figures may be used in connection with speculum types with the lateral screw adjusting and blocking system, since a suitable hollow (15) is provided in the exterior profile of the device (10), for the passage and the free movement of the said screw.

The illumination system of the device (10) comprises, as it is better shown in Figures 2 and 6, two light bulbs (16) and (17) facing towards the speculum (1) and placed at diametrically opposed positions along the curved arm which realises said lighting portion (12). The two bulbs are visible through two corresponding transparent windows, each provided with convex lens. The said windows are included in the sealed back cover (18) (shown in Figures 2 and 6) of the section of the device (10) housing the electric circuit.

The latter, represented with some construction details in Figure 7, comprises first of all a power supply, consisting of the batteries (19). These are housed in the relevant casing (20) at the distal end of the handle portion (11). In particular, in Figures 2, 3 and 6 the casing (20) is shown closed by a back cover (21), while in Figure 7 the back cover is missing. Through the wires (22) and the switch (23), corresponding to the switch button (24) in Figures 4, 5, 8 and 9, the batteries (19) supply energy to the light bulbs (16) and (17). The latter are shown in Figure 7 without the transparent windows which separate them from the external environment. In the embodiment shown, the bulbs (16) and (17) are of the ordinary white light type, but it is also possible to employ particular filters or types of light source able to emit a cold light of a blue-white colour. As noted with reference to the prior art, the latter is specific for evidencing particular abnormal states of the cervix uteri, such as lesions of a neoplastic nature, which are made more visible upon treatment of the tissues with acetic acid.

In the embodiment shown in the figures, the terminal section of the curved arm of the lighting portion (12) is connected to the remainder of the device (10) through a hinge (25), so that the training of the light source (17) may be adjusted as desired during the examination.

In the side elevation views of Figures 8 and 9, as well as in the Figure 4 showing the assembly in the use position, it can be noted that the profile of the light and handle device (10) according to the invention is staggered so as to form a step, the lighting portion (12) being markedly spaced from the speculum mouth (9) on which it is superimposed. This results in the maintenance of a safety distance between the device, which is to be reused, and the patient body, as well as the speculum itself, which is to be disposed of upon the examination.

It is evident from the foregoing that the device according to the invention, through its fixing means, becomes an integral piece with the speculum, thus offering on one hand an ergonomic gripping element for handling the speculum and, on the other hand, a direct light source precisely focused on the zones to be examined. In addition, the device offers the possibility of supporting those accessories that are normally used in a gynaecological examination, such as the speculoscope (optical magnifier) or terminals

of optical fiber instrument. Furthermore, the fixing system proposed is extremely hygienic, as it avoids any need to touch the speculum to throw it away once used. A simple pressure on the pliers means of the device disengages the used speculum, which may be simply dropped from the device.

The present invention has been disclosed with particular reference to some specific embodiments thereof, but it should be understood that modifications and changes may be made by the persons skilled in the art without departing from the scope of the invention as defined in the appended claims.

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**LIGHT AND HANDLE DEVICE FOR VAGINAL SPECULUM**Claims of **WO9825512****CLAIMS**

1. A light and handle device for a vaginal speculum comprising at one end a handle portion (11) having a substantially elongate shape and at the other end a shaped lighting portion (12) having a curved shape and, at an intermediate position between the said two ends, pliers-like fixing means (13) for rigidly connecting the device (10), with the longitudinal axes parallel, with the upper gripping arm (7) of an ordinary speculum (1), the said handle portion (11) having higher dimensions than said upper gripping arm (7), and the said shaped lighting portion (12) having a curved profile which, when the speculum (1) is connected with the device (10), follows from the exterior the outline of the speculum mouth (9), and being provided with one or more light sources (16, 17) placed along its inner edge and facing towards the said speculum mouth (9).
2. Device according to claim 1, wherein the said one or more light sources (16, 17) are powered by disposable or rechargeable batteries (19) housed within the end of the said handle portion (11).
3. Device according to claim 2, wherein the said batteries (19) are housed at the distal end (20) of the said handle portion (11), beyond the length of handle portion (11) which houses, when the speculum (1) is connected with the device (10), the said upper gripping (7) arm of the speculum (1).
4. Device according to any one of claims 1-3, wherein the said one or more light sources (16, 17) are two, placed at diametrically opposed positions along the inner edge of the said shaped lighting portion (12).
5. Device according to claim 4, wherein the first one (16) of the said light sources (16, 17) is placed on the longitudinal axis of the said handle portion (11), and the second one (17) of the said light sources (16, 17) is placed in a diametrically opposed position along the inner edge of the said shaped lighting portion (12), on the extension of the same axis.
6. Device according to claim 5, wherein the said second light source (17) is assembled on a terminal section of the said lighting portion (12) which is connected by a hinge (25) to the remainder of the device (10), so as to be adjustably positioned.
7. Device according to any one of the preceding claims wherein there is provided, at an intermediate position between the said two ends, an elongate hole (14) for the passage and the free movement of the pin (2) of those models of speculum (1) with central pin (2) blocking system.
8. Device according to any one of the preceding claims, wherein, at an intermediate position between the said pliers-like fixing means (13) and the said lighting portion (12), the outline of the device (10) is hollow (15) at least on one side, for the passage and the free movement of the screw of those models of speculum (1) with lateral screw blocking system.
9. Device according to any one of the preceding claims, wherein there is provided, at an intermediate position between the said two ends, a switch (23, 24) for operating the said one or more light sources (16, 17).
10. Device according to any one of the preceding claims, having, in side-elevation view, a substantially step-shaped staggered profile, resulting, when the speculum (1) is connected with the device (10), in a gap between said lighting portion (12) and the upper plane of the said speculum mouth (9).

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